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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,918	02/17/2006	Olivier Neckebroek	CEPF-0006	8401

23377 7590 07/07/2006  
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EXAMINER

KUMAR, SHAILENDRA

ART UNIT PAPER NUMBER

1621

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/539,918	NECKEBROCK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SHAIENDRA -. KUMAR	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 78-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 78-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/19/06, 6/14/06</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 78-87 are pending in this application.

#### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 6/14/06 and 6/8/06 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

#### ***Drawings***

3. The drawings were received on 6/16/06. These drawings are acceptable.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 78-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Lafon (US 4,927,855).

Lafon teach (-) modafinil same as claimed herein. See column 1, lines 61-62. A mere fact that the reference don't mention form A, does not distinguish it from the instant claim inasmuch as it is inherently there.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 78-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafon optionally in view of Broquaire et al (US 6,992,219).

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Lafon teaches (-) modafinil, see column 1, line 61-62. The difference between the reference and herein claimed invention is that the reference does not teach polymorph A.

Broquaire et al teach various forms of polymorphs of modafinil using the similar solvent system. However, the reference fails to mention (-) modafinil.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the process of Broquaire et al in the Lafon process to obtain various polymorphs, including the one claimed herein, because the process of crystallization is similar in both the references and similar to those claimed herein, with the reasonable expectation of achieving a successful form A (-) modafinil, absent evidence to the contrary.

10. Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafon optionally in view of Broquaire et al.

Instant claim is directed to a process of preparing Form I (-)-modafinil, by dissolving (-)-modafinil in hot solvent, rapidly cooling, filtering and drying crystals.

Lafon is teaching a process of preparing (-)-modafinil by crystallizing the modafinil in a solvent and filtering, see column 4. The difference between the reference and herein claimed process is that the reference is not mentioning exact conditions of dissolving and crystallizing.

Broquaire et al is teaching a process of preparing polymorph using various solvent systems and technique, which are similar to those claimed herein.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the process of Broquaire et al crystallization in the process of Lafon, because both the references are directed to a process of preparing crystals of modafinil and Lafon in particular prepares (-)-modafinil. Simple variation of the crystallization process was well within the ordinary skill in the art, absent evidence to the contrary.

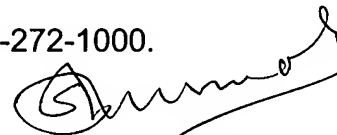
Applicants' remarks and various declarations of Dr. Mellamo, Dr. Peterson, and Dr. Blomsma were fully considered and noted. The declarations are emphasizing that crystallization of modafinil using ethanol can be done under various conditions and results in various forms of modafinil. The declarations emphasize that Lafon **not necessarily** teach Form A of the crystal because the melting point is 153-154<sup>0</sup>C as against 164-166<sup>0</sup>C obtained in herein. It is clear from the declarations that Dr. Mellamo, Dr. Peterson and Dr. Blomsma do not disagree that Lafon reference may teach Form A (-) modafinil, when they mention Lafon modafinil as "not necessarily Form A". With respect to the melting point, exhibit 4, of Dr Mellamo, Form I has melting point 163-164 and Form I/Form II mixture has 156, as well as 160, whereas Form II has 156 as well. It is clear that the melting point is within the error range of few degrees and not consistent. Even Form I has melting point of 159. Thus Lafon's melting point of 153-154 is not much different and is within the experimental error.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571)272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SHAIENDRA - KUMAR  
Primary Examiner  
Art Unit 1621

S.Kumar  
6/27/06